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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,189	01/02/2004	Haitham Matloub	40279-10309	3366

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,189	MATLOUB ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15,16 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,15,16 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 09/14/2006.

Claims 1-19 were previously presented.

Claims 10-14, 17, 18 have been canceled.

Claims 1-9, 15, 16, and 19 are pending and included in the prosecution.

Specification

1. The disclosure is objected to because on page 11, line 18 the word "butyl" is listed within group consisting of polymers, while "butyl" is chemical group and not a polymer. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 3, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 3 as amended as well as the newly added claim 15 are reciting new matters that are not described in the specification as originally filed. Claims 2 recites the limitation "up to 30 days" and claim 15 recites the limitation "up to 14 days" and these recitations permits periods less than 14 days. Nowhere in the specification had applicants disclosed period less than 14 days. On page 18, line 5, applicants disclosed "from about 14 to about 30 days". Therefore applicants have no support for the limitations "up to 14 days" or "up to 30 days" that have open-ended lower limit. With regard to claim 3, the claim recites the limitation "up to 300 microns", and these limitations permit values below 200 microns. Nowhere in the specification had applicants disclosed values less than 200 microns. On page 11, line 10, applicants disclosed "about 200 to about 300 microns". Therefore applicants have no support for the limitations "up to 300 microns" or "up to 200 microns" that have open-ended lower limit.

Response to Arguments

4. Applicants traverse the new matter rejection by referring to the following statements in the specification for support for claims 2 and 15: page 15, lines 10-14 "antioxidant would be released in time period ranging from 0 to about 14 days"; and the disclosure on page 11, lines 11-14 that "therapeutic agent can be release for as much as about 14 to about 30 days".

In response to the above argument, it is noticed that applicants are referring to support for different issues. On page 15, lines 10-14, applicants disclosed the onset of start of release of the antioxidant that started from 0-14 days. That disclosure does not support the limitations of claim 2 that recites the period of release the active agent for a period up to about 14 to about 30 days, and does not support claim 15 that recites the period of release the active agent for a period up to 14 days, and the claims encompass less than 14 days. On page 11, lines 11-14, applicants disclosed that the therapeutic agent can be released for period of about 14 to about 30 days. In either texts of the specification, no support for the limitations of claims 2 and 15 that the sheet is capable to release the active agent for a period up to about 14 to about 30 days or up to 14 days, respectively.

Regarding claim 3, applicants have failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 5-7, 9, 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 2002/0128578 ('578), US 5,352,508 ('508), and US 6,183,770 (770).

US '578 teaches medical article comprises multiple sheets comprising microchannels useful for wound dressing and drug delivery dressing (abstract; paragraphs 0022, 0073, 0121). The article comprises layers have the microchannels that are made of polyurethane or polyvinyl acetate to facilitate the delivery of medicaments (paragraphs 0023, 0047, 0048), and absorbent layer made of foam (paragraphs 0107, 0109). The medicaments delivered by the article comprises growth factor (paragraph 0120).

US '578 does not teach that the layer comprises the microchannels surround the absorbent layer, or the medicaments are hold in the microchannels.

US '508 teaches wound dressing comprising net substrate encapsulated in hydrophilic tacky resin coating leaving the apertures in the net substrate unoccluded to prevent skin occlusion or damage to the healthy skin (abstract; col.1, lines 26-30; col.2, lines 57-61). Coating is polyurethane that may contain active agents such as silver sulphadiazine (col.2, lines 62-64; col.3, lines 29-33). The coated substrate is laminated between two release liners (col.5, lines 52-54).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a medical article comprises layer comprises microchannels and foam layer as disclosed by US '578, and encapsulate the foam layer with the layer comprising microchannels as taught by US '508, motivated by the teaching of US '508 that encapsulating the porous net substrate with an apertured layer prevents skin occlusion or damage to the healthy skin, with reasonable expectation of having medical article comprising foam layer encapsulated in apertured layer or layer comprising microchannels that prevents occlusion or damage to the healthy skin to which the article is applied.

The combination of US '578 and US '508 does not teach the medicaments are held in the microchannels.

US '770 teaches patch to deliver active agents locally to the skin in a manner to minimize the deleterious effects of adhesives on the active agents (abstract). The patch contains the active agents in apertures (col.6, lines 46-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a medical article comprises layer comprises

microchannels encapsulating a foam layer as disclosed by the combined teaching of US '578 and US '508, and further hold the active agents in the microchannels as disclosed by US '770, motivated by the teaching of US '770 that such a structure minimizes the deleterious effects of adhesives on the active agents, with reasonable expectation of having medical article comprises microchannels that hold the active agents to be delivered to the skin with minimal deleterious effects on the active agents.

The combination of US '578, US '508 and US '770 does not teach the period of release of the therapeutic active agent.

The period of delivery of the therapeutic agent can be manipulated by the skilled artisan according to the polymer, active agent and to the condition to be treated.

8. Claims 3, 4, 8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '578, US '508 and US '770 and further in view of US 6,326, 410 ('410).

The combined teachings of US '578, US '508 and US '770 are discussed above.

However, the combination of the references does not teach the pore sizes as claimed in claim 3, or the material of the foam layer as claimed in claims 4, 8 and 19.

US '410 teaches polyurethane foam having pore sizes between 0.1 to 0.6 mm, i.e. 100 to 600 μm, that is suitable for wound contacting because it has low adherence and can deliver active agents to the wound (abstract; col.3, lines 14-15, 66-67; col.4, lines 1-3). The pore sizes disclosed by the reference encompass the sizes claimed by applicants, 200-300 μm.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising foam encapsulated with layer comprises microchannels that hold active agents as disclosed by the combined teachings of US '578, US '508 and US '770, and replace the foam layer with polyurethane foam having pore sizes between 100-600 μm as disclosed by US '410, motivated by the teachings of US '410 such polyurethane foam has low adherence to the skin and can deliver active agents to the wound, with reasonable expectation of having wound dressing comprising porous polyurethane foam polymer material that deliver active agent to wound site without being adherent to the wound.

Claim Objections

9. Claim 9 is objected to because of the following informalities: the term "platelet derived growth factor" is misspelled as "plate derived growth factor". Appropriate correction is required.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali